Re-evaluation Note REV2010-06

Update of Re-evaluation of *Bacillus thuringiensis*

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Health Canada's Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of *Bacillus thuringiensis* and has concluded that continuing registration for this active ingredient and associated end-uses is acceptable, provided that certain mitigation measures are adopted. Additional data requirements are identified. Summaries of the data and information reviewed during the re-evaluation and the proposed regulatory decisions were published in the Proposed Acceptability for Continuing Registration document PACR2006-09, *Re-evaluation of Bacillus thuringiensis*, dated 16 November 2006, in compliance with Section 28(2) of the *Pest Control Products Act (PCPA)*.

The decision statement (RVD2008-18), which was published on 6 May 2008, includes the reasons for the decision as well as a summary of the comments received on the proposed decision. The conditions for continuing registration of *Bacillus thuringiensis* and its associated end-uses include the implementation of mitigation measures, and the provision of data by the registrant of the technical to address identified deficiencies.

Following the publication of RVD2008-18, several stakeholders filed Notices of Objection in July 2008, regarding the PMRA's decision to continue the registration of *Bacillus thuringiensis (The Notices and PMRA's response to the Notices are available at the PMRA's Public Registry under Programs and Special Actions/Reconsideration)*. The PMRA has carefully reviewed this information, and concluded that a reconsideration of the re-evaluation decision for *Bacillus thuringiensis* is not warranted. However, some mitigation measures such as label statements have been revised. The revised labelling statements describing the acceptable uses and conditions of use for *Bacillus thuringiensis* end-use products are summarized in Appendix I.

Appendix I Revised Label Amendments for Products Containing *Bacillus thuringiensis*

NOTE: This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary personal protective equipment that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

Canadian labels containing *Bacillus thuringiensis* (*Bacillus thuringiensis* subspecies *kurstaki* (Btk), *B. thuringiensis* subsp. *israelensis* (Bti) and *B. thuringiensis* subsp. *tenebrionis* (Btt)) must be amended to include the following statements to further protect handlers, bystanders and the environment.

On the principal display panel

The guarantee sections of the labels for the technical grade active ingredients and end-use products must specify a company-specific strain (or other appropriate) designation of *B. thuringiensis* for the active ingredient.

Until a recognized global potency standard for Btk-based insecticides is established, the guarantee sections of the labels for technical and end-use Btk products must not imply a standardized or international potency unit (e.g. billion international units).

The labels for the technical and end-use products must include the signal words "POTENTIAL SENSITIZER" and "CAUTION EYE IRRITANT". The "CAUTION EYE IRRITANT" statement may be waived if indicated by eye irritation test data or an acceptable rationale.

The labels must also include the following:

Date of manufacture: _____

The labels for **domestic class end-use products** must include or be updated to include the following statement: "KEEP OUT OF REACH OF CHILDREN".

On the secondary display panel

a) The labels for **technical class products** must include the following statements of precaution and personal protective equipment.

> KEEP OUT OF REACH OF UNAUTHORIZED PERSONNEL.
> MAY CAUSE SENSITIZATION. CAUTION EYE IRRITANT.
> Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks, eye goggles and a NIOSH-approved respirator with any N-95, R-95, or P-95 filter for biological products when handling or mixing/loading the product and during

all clean-up/repair activities. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The "CAUTION EYE IRRITANT" and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

b) The labels for **domestic class end-use products** must include or be updated to include the following statement of precaution and personal protective equipment.

> MAY CAUSE SENSITIZATION. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks as well as eye goggles when handling or applying the product and during all clean-up activities.

The "CAUTION EYE IRRITANT" and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

c) The labels for **commercial class end-use Btk and Btt products** must include or be updated to include the following statement of precaution and personal protective equipment.

> KEEP OUT OF REACH OF CHILDREN. MAY CAUSE SENSITIZATION. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes plus socks, eye goggles and a NIOSH-approved respirator with any N-95, R-95, or P-95 filter for biological products when handling, mixing/loading or applying the product and during all clean-up/repair activities. When applicators use closed systems (e.g. enclosed cabs) the personal protective equipment requirements may be reduced or modified. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The "CAUTION EYE IRRITANT" and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

d) The labels for **restricted class Btk and Btt end-use products** must include the following statements of precaution and personal protective equipment.

> KEEP OUT OF REACH OF UNAUTHORIZED PERSONNEL. MAY CAUSE SENSITIZATION. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks, eye goggles and a NIOSH-approved

respirator with any N-95, R-95, or P-95 filter for biological products when handling, mixing/loading or applying the product and during all clean-up/repair activities. When applicators use closed systems (e.g. enclosed cabs) the personal protective equipment requirements may be reduced or modified. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The "CAUTION EYE IRRITANT" and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

e) The labels for **commercial and restricted Bti** end-use products must include the following statements of precaution and personal protective equipment.

KEEP OUT OF REACH OF UNAUTHORIZED PERSONNEL. MAY CAUSE SENSITIZATION. CAUTION EYE IRRITANT. Avoid contact with skin, eyes or clothing. Avoid breathing dust/spray mist. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes and socks, eye goggles and a NIOSH-approved respirator with any N-95, R-95, or P-95 filter for biological products when handling, mixing/loading or applying the product and during all clean-up/repair activities. Applicators may remove gloves, eye goggles and respirators if the design and delivery of the application apparatus reduces exposure to a negligible level (e.g. backpack sprayer with application wands that apply product directly over water surface). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The "CAUTION EYE IRRITANT" and eye goggle requirement may be waived if indicated by eye irritation test data or an acceptable rationale.

f) The labels for the **technical class and end-use products** must include or be updated to include the following statements under the heading **FIRST AID**.

If on skin or clothing: Rinse skin immediately with plenty of water. Remove contaminated clothing and wash separately before reuse. If irritation occurs and persists or is severe, seek medical attention.

If in eyes:	Hold eye open and rinse slowly and gently with water. Remove contact lenses, if present, then continue rinsing eye. If irritation occurs and persists or is severe, seek medical attention.
If inhaled:	Move to fresh air, apply respiration if needed and seek medical attention.
If swallowed:	Rinse mouth and throat with copious amounts of water. DO NOT induce vomiting. Promptly contact a physician or poison control centre. DO NOT give anything by mouth to an unconscious person.
General:	Seek medical attention if irritation or signs of toxicity occur and persist or is severe. Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

The TOXICOLOGICAL INFORMATION must include the statement "Treat symptomatically."

g) The labels for **commercial and restricted class end-use products** must include the following statement under the heading Resistance-Management Recommendations.

> For resistance management, please note that [insert product name] contains a Group 11 insecticide. Any insect population may contain individuals naturally resistant to [insert product name] and other Group 11 insecticides. The resistant individuals may dominate the insect population if this group of insecticides is used repeatedly in the same site. Other resistance mechanisms that are not linked to site of action but specific for individual chemicals, such as enhanced metabolism, may also exist. The following appropriate resistance management strategies should be followed to delay insecticide resistance:
>
> - Where possible, rotate the use of [insert product's name] and other Group 11 insecticides with different groups that control the same pests in a site.
> - Insecticide use should be based on an Integrated Pest Management program that includes scouting, record keeping, and considers cultural, biological and other chemical control practices.
> - Monitor treated pest populations for resistance development.

- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance management and/or integrated pest management recommendation for specific site and pest problems in your area.

- For further information or to report suspected resistance, contact [insert registrant's name] at [insert registrant's contact information].

h) The labels for all end-use products must include the following statements under **DIRECTIONS FOR USE**.

> DO NOT allow spray mixture to stand in the tank for more than 18 hours.

[This time period may be extended if there are supporting data and is not required on ready-to-use product labels.]

The labels for all end-use products must include the following statements regarding storage and shelf life.

> In order to ensure microbial purity and potency, [insert product's name] should be stored in the original container at [insert temperature as supported by data] and used within [insert time period as supported by test data] of the date of manufacture.

[In the absence of storage stability data, the label must direct users to store at temperatures between 5–15°C and to use the product within 6 months from the date of manufacture.]

Unless supported by efficacy data, all end-use product labels must include a "DO NOT apply by any type of irrigation system" statement.

i) The labels for all end-use products that have aerial applications must include the following statements.

> **"Aerial Application Instructions:**
> Apply only by fixed-wing or rotary aircraft equipment that has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label.

Label rates, conditions and precautions are product-specific. Apply only at the rate recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment. Ensure uniform application by using appropriate marking devices and/or electronic guidance equipment.

Use Precautions:
Apply only when meteorological conditions at the treatment site allow for complete and even coverage. Apply only when meteorological conditions are in compliance with local and/or provincial authorities.

Operator Precautions:
DO NOT allow the pilot to mix product to be loaded onto the aircraft. However, loading of premixed product with a closed system is permitted. It is desirable that the pilot have communication capabilities at each treatment site at the time of application.

The field crew and the mixer/loaders must wear the personal protective equipment described in the PRECAUTIONS section of this label. When handlers/loaders use closed systems to load the product onto the aircraft, the handler requirement for eye goggles and a NIOSH-approved respirator/mask with any N-95, R-95, or P-95 filter for biological products may be waived. When reduced personal protective equipment is worn, the respirator/mask and eye goggles must be immediately available for use in an emergency such as a spill or equipment breakdown.

All personnel on the job site must wash hands and face thoroughly before eating and drinking. Protective clothing must be washed before reuse. Decontaminate aircraft cockpits and vehicle cabs if contamination occurs.

Product Precautions:
Read and understand the entire label before opening this product. If you have questions, call the manufacturer at [insert toll free number] or obtain technical advice from the distributor or from your provincial agricultural or forestry representative. Application of this specific product must meet and/or conform to the aerial uses and rates on this label."

j) The labels for *B. thuringiensis* subsp. *kurstaki* and *B. thuringiensis* subsp. *tenebrionis* end-use products must include the following statement under the **DIRECTIONS FOR USE** section.

> DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes. As this pesticide is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

k) The labels for *B. thuringiensis* subsp. *israelensis* end-use products must include the following statement under the **PRECAUTIONS** section.

> DO NOT apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

l) Any reference to specific users (e.g. homeowners, cottage owners, rural dwellers) must be deleted from the labels of *B. thuringiensis* subsp. *israelensis* domestic class end-use products, and the following statement must be included in the **DIRECTIONS FOR USE** section.

> [insert name of product] is for use only when mosquito larvae are present in:
>
> - standing water wholly confined to the property of the user where there is no existing outflow beyond the property limits that remains for more than a week and cannot be drained (for example, flooded depressions, ponds)
>
> - containerized water (for example, bird baths, flower planters, discarded tires, ornamental ponds and rain barrels) that cannot be emptied, drained, flushed or changed at least weekly
>
> DO NOT apply this product to any water that is designed to flow beyond your property limits (for example, ditches, drains, rain gutters or catch basin sumps that flow into weeping tile beds or municipal storm drain systems). BEFORE APPLYING THIS PRODUCT to a water body where there is a possibility of outflow beyond your property limits, contact your provincial/territorial regulatory authority as a permit may be required.
>
> To help prevent mosquito infestations on your property, get rid of mosquito breeding sites. Do this by emptying, flushing or draining containerized and standing water, wherever practical, at least weekly or more frequently if mosquito larvae are present. For example, remove leaf litter from rain gutters, drill holes in bottoms of tire swings or discarded tires, empty water collected on pool

covers, turn over wheelbarrows and other containers, empty trapped water from recycling bins or trash containers, cover rain barrels with fly screen netting, replace water in bird baths and chlorinate swimming pools.

m) The following must be deleted from labels of commercial class products containing *B. thuringiensis* subsp. *israelensis*.

- any reference to specific users, e.g. farmers, cottage owners, rural dwellers; and
- any reference to wholly contained waters, e.g. standing water wholly contained within the property of the user.

In addition, the labels of these products must include the following statement:

Consult provincial/territorial pesticide regulatory officials for required authorization.